

REMARKS

After entry of this amendment, claims 1, 2, 4, 7, 9, 14, 15, 19, 25, 26, 28, 29, 32, 35, 36, 39-41, 43-48, 51, 54, 55, 58-62, and 64 will be pending for the Examiner's review and consideration. Claims 14, 28, 44, 47, 59 and 60 have been amended. No new matter has been added. Claims 27, 42, and 63 have been canceled without prejudice. Claims 30, 31, 33, 34, 37, 38, 49, 50, 52, 53, 56, and 57 have been withdrawn with traverse as being subjected to a non-elected species. Reconsideration and allowance of the present application in view of the above amendments and the following remarks is respectfully requested.

This amendment responds to the office action mailed April 30, 2004. In the office action the Examiner:

- withdrew claims 30, 31, 33, 34, 37, 38, 49, 50, 52, 53, 56, and 57 as being drawn to a non-elected species;
- objected to the drawings under 37 C.F.R. §1.83(a) for failing to show every feature of the invention specified in the claims;
- objected to the specification under 37 C.F.R. §1.75(d)(1) and MPEP § 608.01(o) for failing to provide proper antecedent basis for the claimed subject matter; and
- rejected claims 1, 2, 4, 7, 9, 14, 15, 19, 25-29, 32, 35, 36, 39-48, 51, 54, 55, and 58-64 under 35 U.S.C. § 103(a) as being unpatentable over United States Patent No. 5,776,197 to Rabbe *et al.* ("Rabbe") in view of International Publication No. WO 98/29047 to Zucherman *et al.* ("Zucherman").

Dependent Claims 30, 31, 33, 34, 37, 38, 49, 50, 52, 53, 56, and 57

Dependent claims 30, 31, 33, 34, 37, 38, 49, 50, 52, 53, 56, and 57 were withdrawn from consideration as being directed to a non-elected species. Applicants agree to withdraw claims 30, 31, 33, 34, 37, 38, 49, 50, 52, 53, 56, and 57 from consideration only with the understanding that claims 30, 31, 33, 34, 37, 38, 49, 50, 52, 53, 56, and 57 shall be restricted to this species only if no claim finally held to be allowable is held generic. Applicants believe that pending independent claims 1, 40, and 59 are generic at least with respect to

Figures 4b, 4c, 8 and 9 (all of which depict an end member having, *inter alia*, a plurality of tabs), and thus, canceling claims 30, 31, 33, 34, 37, 38, 49, 50, 52, 53, 56, and 57 is improper.

Moreover, Applicants believe that withdrawing claims 30, 31, 33, 34, 49, 50, 52, and 53 is especially improper since as stated in the specification on page 3, line 34, "FIG. 9 shows a perspective view of the bottom of an end member according to the present invention." It is respectfully submitted that one skilled in the prior art would recognize that Fig. 9 is and could be a bottom view of the end member depicted in at least Fig. 4b and 4c.

Furthermore, Applicants respectfully submit that at least with regards to Figures 4b, 4c, 8 and 9 (directed to an end member having, *inter alia*, a plurality of tabs) that to search and examine the subject matter of Figures 4b, 4c, 8, and 9 together would not be a serious burden on the Examiner especially since the only difference between Figures 4b, 4c, 8, and 9 is the overall shape of the implant and location of the channels. The M.P.E.P. § 803 states:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Applicants contend that a search and examination of claims 30, 31, 33, 34, 37, 38, 49, 50, 52, 53, 56, and 57 with regards to, at least, Figures 4b, 4c, 8, and 9 could be made without serious burden and that claims 30, 31, 33, 34, 37, 38, 49, 50, 52, 53, 56, and 57 should not be withdrawn from the present application. Moreover, Applicants believe that the classifications of the invention in at least Figures 4b, 4c, 8 and 9 are the same, and the field of search will be the same, thus Applicants believe that canceling claims 30, 31, 33, 34, 37, 38, 49, 50, 52, 53, 56, and 57 from the present application is especially improper. *See* MPEP 808.02.

As such, Applicants respectfully submit that claims 30, 31, 33, 34, 37, 38, 49, 50, 52, 53, 56, and 57 should not be withdrawn from the present application as independent claims 1, 40, and 59 are generic, at least with regards to Figures 4a, 4b, 8, and 9 since the Applicants respectfully submit that the only difference between Figures 4b, 4c, 8, and 9 is the overall shape of the implant and location of the channels. Accordingly, Applicants respectfully request that claims 30, 31, 33, 34, 37, 38, 49, 50, 52, 53, 56, and 57 be examined in the subject application.

Drawing Objection

The drawings were objected to under 37 C.F.R. §1.83(a) for failing to show every feature of the invention specified in the claims. Specifically, the Examiner objected to the drawings for failing to show "an implant consisting of two end members." In response to the Examiner's objections to the drawings, Applicants respectfully submit that one skilled in the art would recognize that the present application is directed to, *inter alia*, an end member for engaging an intervertebral spacer. That is, as described in the Background of the Invention, in order to correct a variety of spinal disorders, often times a vertebra must be removed, either completely or partially, *i.e.*, a corpectomy. One way to correct a spinal disorder is to remove the vertebra and to replace the vertebra with an intervertebral spacer which is sized and configured to fill the void left by the removed vertebra. One problem with such bone fusion implants is subsidence of the bone fusion implant into the patient's vertebra - that is, excessive sinking of the ends of the bone fusion implant into the remaining vertebra of the patient. One solution to subsidence is to increase the surface area of the bone fusion implant which contacts the patient's vertebra. Therein, as described throughout the specification, an end member may be used wherein the end member has a first portion with a top surface adapted and configured to engage the vertebrae and a second portion configured and dimensioned to be inserted into a bore formed in the bone fusion implant. Thus, it is respectfully submitted that one skilled in the art would recognize that in order to prevent subsidence of the bone fusion implant, an end member may have to be placed on either or both sides of the bone fusion implant. Only in this manner could one prevent subsidence of the implant into each vertebrae.

Moreover, as stated on page 6, lines 28-29, with regards to Figure 5, "[i]t should be noted that as an end member would ordinarily be used on each end of [a] bone fusion implant ..." Thus, it is respectfully submitted that the as-filed specification does support and one of ordinary skill in the art would recognize that the present invention supports the proposition that an end member could be placed on both sides of the bone fusion implant.

However, in an effort to expedite prosecution of the present application, the Applicants respectfully withdraw claims 27, 42, and 63 from consideration without prejudice to be pursued in a continuation, divisional, and/or continuation-in-part if the Applicants so desire. It should be noted that under no circumstances should the cancellation of claims 27, 42, and 63 be perceived as an admission, as it is respectfully submitted that one skilled in the

art would recognize from the disclosure of the application that an end member could be placed on both ends of the intervertebral spacer.

It is respectfully submitted that in view of the Applicants' cancellation of claims 27, 42, and 63, the Examiner's objection to the drawings is moot. Therefore, it is respectfully requested that this objection be withdrawn.

Specification Objection

The specification was objected to under 37 C.F.R. §1.75(d)(1) and MPEP § 608.01(o) for failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Examiner objected to the specification for failing to provide support for "two end members with an implant," a "top surface having no through holes," "a dimension of the longitudinal axis being identical to a dimension of the lateral axis," "a dimension of the major axis being larger than a dimension of the minor axis," and "outer cross-sectional dimensions for the spacer body and the first portion of the end member being identical when the second portion of the end member is inserted."

It is respectfully submitted that the Examiner's objection to the specification for failing to provide support for "two end members with an implant" in light of the above discussion is moot. Therefore, it is respectfully requested that this objection be withdrawn.

It is respectfully submitted that the specification as filed provides support for the proposition that the top surface of the end member has no through holes in between the outer perimeter of the end member and the annular opening formed in the center of the end member. Specifically, as shown in Figures 1, 3, 4a, 4b, 4c, and 6 the top surface of the end member is void of any through holes except for the annular opening. However, in an effort to expedite prosecution of the present application, the Applicants have amended claims 28, 47, and 59 without prejudice to be pursued in a continuation, divisional, and/or continuation-in-part if the Applicants so desire. It should be noted that under no circumstances should the amendment of claims 28, 47, and 59 be perceived as an admission that the specification lacks support, as it is respectfully submitted that the Figures 1, 3, 4a, 4b, 4c, and 6 provide ample support for the proposition that the top surface of the end member is devoid of any through holes aside from the annular opening. It is respectfully submitted that in view of the Applicants' amendment of claims 28, 47, and 59, the Examiner's objection to the specification

lacking support for the proposition of a "top surface having no through holes" is moot. Therefore, it is respectfully requested that this objection be withdrawn.

It is respectfully submitted that the specification as filed provides support for the proposition that "a dimension of the longitudinal axis being identical to a dimension of the lateral axis," and for the proposition that "a dimension of the major axis being larger than a dimension of the minor axis." Specifically, as stated on page 2, lines 22-23, "[t]he top surface can made in any suitable cross-sectional shape, such as oval, oblong, or round, and may be annular or solid." Moreover, additional support for "a dimension of the longitudinal axis being identical to a dimension of the lateral axis" can be found on page 4, lines 17-18 where the specification states the "[t]op surface 18 is shown in FIG. 1 with a round shape" and in Figures 1, 6, 8, 10, 12, and 13 where a substantially circular end member is depicted. Similarly, additional support for "a dimension of the major axis being larger than a dimension of the minor axis" can be found on page 5, lines 25-27 where the specification states the "[e]nd member 110 has an oval or oblong shape" and in Figures 3, 4a, 4b, 4c, 7, and 9. It is respectfully submitted that one skilled in the art would recognize that the end member depicted in Figure 9 is not limited to an oval shape and that, as described in the specification, other shapes could be used and be within the species as depicted in Figure 9. It is respectfully submitted that these objections be withdrawn.

It is respectfully submitted that the specification as filed provides support for the proposition that the outer cross-sectional dimensions for the intervertebral spacer body and the first portion of the end member is substantially identical when the second portion of the end member is inserted into the spacer body. Specifically, as shown in Figure 2, the outer cross-sectional diameter of the intervertebral spacer 22 is substantially identical to the outer cross sectional diameter of the first portion 12 of end member 10 when the second portion 14 of end member 10 is inserted in a bore formed in the top of the intervertebral spacer 22. It is respectfully submitted that these objections be withdrawn.

Independent Claims 1, 40, and 59

Independent claims 1, 40, and 59 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Rabbe in view of Zucherman. Independent claims 1, 40, and 59 are directed to, *inter alia*, an end member comprising a first portion with a top surface adapted and configured to engage the bone, a second portion configured and dimensioned to be inserted into a bore of an implant; and a shoulder joining the first and second portions and

sized to rest on an end edge of the implant when the second portion is inserted in the bore of the implant; wherein the second portion comprises a plurality of resilient tabs flexing inward upon insertion of the second portion in the implant and flexing back outward to secure the end member to the implant.

Applicants respectfully submit that the Examiner's combination of Rabbe and Zucherman to render obvious independent claims 1, 40, and 59 is impermissible hindsight reconstruction. That is, in order to establish a prima facie case of obviousness, the Examiner bears the burden of establishing three basic criteria. First, the Examiner must show that there was some suggestion or motivation, either in the references themselves or in the knowledge generally available to one skilled in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references must teach or suggest all of the claim limitations. See MPEP § 2142; *In re Vaack*, 947 F.2d 488 (Fed. Cir. 1991).

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on the applicant's disclosure. Therefore, making a legal determination of obviousness does not mean that one can "pick and choose among the individual elements of assorted prior art references to recreate the claimed invention." *Smithkline Diagnostics, Inc. v. Helena Laboratories Corp.*, 858 F.2d 878, 8 USPQ2d 1468 (Fed. Cir. 1988). Rather, the Examiner must show, not that each element existed in the prior art, but that some teaching or suggestion in the references made obvious the invention as a whole. *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 15 USPQ2d 1321 (Fed. Cir. 1990).

It is respectfully submitted that the Examiner has not satisfied the burden of proving that there was some suggestion or motivation to combine Rabbe (which is directed to an implant for the replacement of a vertebra body and which discloses a threaded cylinder body 21, threaded endplates 22 and end caps 23 wherein the threaded cylindrical body 21 has external threads 32 sized and configured to engage the threaded endplates 22 and the threaded endplates 22 have threaded openings 39 for receiving a set screw 24 for securing the endplates 22 to the cylinder body 21) with Zucherman (which is directed an implant for insertion into the space in between a patient spinous processes and which discloses an implant 630 comprising a central body 632 and a plunger 638 wherein the central body 632 has a first arm 634 and a second arm 636, and the plunger 638 has a third arm 640 and a fourth arm 642. The plunger 638 being slidably received within the central body 632 from a

first position where the third and fourth arms 640, 642 are located inside the body 632 to a second position where the third and fourth arms 640, 642 extend and radially project from the body 632). It is respectfully submitted, that there is absolutely no suggestion or motivation in either reference to modify the implant of Rabbe to include the resilient arms of Zucherman. Moreover, it is submitted that there was no suggestion or motivation within the knowledge generally available to one skilled in the art at the time of filing this application to modify the implant of Rabbe to include the resilient arms of Zucherman. In fact, it is respectfully submitted, that to modify Rabbe to include a plurality of tabs would require one to completely redesign the entire implant of Rabbe which is designed and functions based on the use of a threaded connection between the end cap and threaded cylindrical body. Therefore, modifying the implant of Rabbe to include the resilient arms of Zucherman would in essence require one to totally redesign the implant disclosed in Rabbe.

Rather, it is respectfully submitted, that the Applicants through their own effort and expense derived the device as claimed in independent claims 1, 40, and 59, respectively. It is respectfully submitted that without the benefit of the Applicants' disclosure, it would not be obvious for one of ordinary skill in the art to redesign Rabbe to include a plurality of resilient tabs. One cannot simply use the Applicants' disclosure as a blueprint to pick and choose among the individual elements of assorted prior art references in order to combine the right references in the right way to achieve the Applicants' claimed invention. *Grain Processing Corp. v. American Maize-Products Corp.* 840 F.2d 902 (Fed. Cir. 1988). Thus, it is respectfully submitted that independent claims 1, 40, and 59 are allowable over the cited prior art. Withdrawal of these rejections and allowance of claims 1, 40, and 59 is respectfully requested.

Dependent claims 2, 4, 7, 9, 14, 15, 19, 25, 26, 28, 29, 32, 35, 36, 39, 41, 43-48, 51, 54, 55, 58, 60-62, and 64 all ultimately depend from independent claims 1, 40, and 59 and thus, it is respectfully submitted that these claims are equally allowable. Allowance of these claims is therefore respectfully requested.

In light of the above amendments and remarks, it is respectfully submitted that claims 1, 2, 4, 7, 9, 14, 15, 19, 25, 26, 28, 29, 32, 35, 36, 39-41, 43-48, 51, 54, 55, 58-62, and 64 are now in condition for allowance, and the Examiner is respectfully requested to reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney at 212-326-7883, if a telephone call could help resolve any remaining issues.

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Respectfully submitted,

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